

REMARKS — TABLE OF CONTENTS

I.	STATUS OF CLAIMS	22
II.	ISSUES TO BE REVIEWED	22
III.	ARGUMENT: ART OF RECORD DOES NOT ESTABLISH <i>PRIMA FACIE</i> CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD	23
A.	Legal Standards for Patentability	23
1.	What a Reference “Teaches” Is a Question of Fact	25
2.	MPEP Standards for Determining Anticipation	28
3.	MPEP Standards for Determining Obviousness	30
a)	Interpreting a Claim at Issue	31
b)	Definition of One or More Prior Art Reference Components Relevant to the Claim at Issue	32
c)	Ascertainment of Differences between Prior Art Reference Components and Claim at Issue; Teaching to Modify and/or Combine Prior Art Reference Components to Remedy Those Differences in Order to Achieve Recitations of Claim at Issue.....	33
B.	Technical Material Cited by the USPTO Does Not Show/Suggest Recitations of Independent Claim 42 and Dependent Claims 2-41 and 100 as Presented Herein; Notice of Allowance of Same Respectfully Requested.....	36
1.	Independent Claim 1	37
a)	The USPTO-Cited Technical Material Fails to Recite Several Express Terms of Independent Claim 1 and Therefore the USPTO Has Not Met Its Burden to Establish a <i>Prima Facie</i> Case of Unpatentability for Independent Claim 1	38
b)	The USPTO is Characterizing/Asserting U.S. Pat. No. 6,385,472 (“Hall”) to “Teach” the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a <i>Prima Facie</i> Case of Unpatentability for Independent Claim 1	40
(1)	The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion	

	That Hall “Teaches” Recitations of Independent Claim 1	41
(2)	The USPTO Characterization/Assertion Appears to be Based on Inadvertent Impermissible Hindsight, Personal Knowledge, or Official Notice; Applicant Requests Issuance of Notice of Allowability	47
c)	The USPTO-Suggested Modifications/Combinations to Meet the Recitations of Independent Claim 1 Are a “Mere Conclusory Statement” Without Evidentiary Support/Change the Principle of Operation of Components of Cited References/Render Such Components Unfit for Intended Purpose; No Teaching to Combine/Modify Components as a Matter of Law.....	48
(1)	The USPTO Assertions Regarding A Teaching to Modify/Combine to Meet the Recitations of Independent Claim 1 Are Based on “Mere Conclusory Statements” Without Evidentiary Support	49
(2)	The USPTO-Suggested Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.	51
2.	Dependent Claims 2-41 and 100 Patentable for at Least Reasons of Dependency from Independent Claim 1	54
3.	Dependent Claim 2 is Independently Patentable	55
4.	Dependent Claim 15 is Independently Patentable	66
5.	Dependent Claim 16 is Independently Patentable	89
IV.	CONCLUSION.....	112

I. STATUS OF CLAIMS

Claims 1-100 are currently pending.

Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, and 33-41 are rejected under 35 USC 102(b) as being anticipated by U.S. Pat. No. 6,385,472 (“Hall”). *See* Office Action, p. 2 (29 October 2009).

Claims 7, 22 and 26 are rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,385,472 (“Hall”). *See* Office Action, p. 3 (29 October 2009).

Claims 9, 11-20, 28, 29, and 31 are rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,385,472 (“Hall”) in view of U.S. Pat. No. 6,936,003 (“Iddan”). *See* Office Action, p. 4 (29 October 2009).

Claim 100 is rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,385,472 (“Hall”) in view of U.S. Pat. Pub. 2005/0027236 (“Doak”). *See* Office Action, p. 6 (29 October 2009).

Without any prejudice or disclaimer, moreover, Applicant hereby amends claims 1, 2, 15, 16, and 41. These changes were made to further clarify patentable subject matter set forth in the specification as originally filed. No new matter has been added.

II. ISSUES TO BE REVIEWED

The issues in this response relate to whether the art of record establishes a *prima facie* case of the unpatentability of Applicant’s claims. For reasons set forth elsewhere herein, Applicant respectfully asserts that the art of record does not establish a *prima facie* case of the unpatentability of any pending claim.¹

¹ Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 (“A practitioner should represent a client zealously within the bounds of the law.”); 37 C.F.R. § 10.84 (“[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part.”); and 37 C.F.R. § 10.76 (“A practitioner should represent a client competently.”). For these and other reasons, this document

Accordingly, Applicant respectfully requests that the USPTO hold all pending claims allowable for at least the reasons described herein, and issue a Notice of Allowance on same.

III. ARGUMENT: ART OF RECORD DOES NOT ESTABLISH *PRIMA FACIE* CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD

The USPTO has stated, “Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, and 33-41 are rejected under 35 USC 102(b) as being anticipated by U.S. Pat. No. 6,385,472 (“Hall”). Office Action, p. 2 (29 October 2009).

In response, Applicant respectfully asserts herein that, under the MPEP and legal standards for patentability as set forth below, the art of record does not establish a *prima facie* case of the unpatentability of Applicant’s claims at issue. Specifically, Applicant respectfully shows below that the art of record does not recite the text of Applicant’s claims at issue, and hence fails to establish a *prima facie* case of unpatentability. Accordingly, Applicant respectfully requests that the USPTO withdraw its rejections and hold all claims to be allowable over the art of record.

A. Legal Standards for Patentability²

The MPEP states as follows: “the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the

notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the Examiner’s behalf.

² Applicant is aware that Examiner is familiar with the MPEP standards. Applicant is merely setting forth the MPEP standards to serve as a framework for Applicant’s arguments following and to ensure a complete written record is established. Should Examiner disagree with Applicant’s characterization of the MPEP standards, Applicant respectfully request correction.

applicant is entitled to grant of the patent.” *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)); *In Re Glaug*, 283 F.3d 1335, 62 USPQ2d 1151 (Fed. Cir. 2002) (“During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent.”). Accordingly, unless and until an examiner presents evidence establishing *prima facie* unpatentability, an applicant is entitled to a patent on all claims presented for examination.

For example, in making an obviousness rejection, the evidence required must come in the form of particular findings: “[b]road conclusory statements standing alone are not ‘evidence’.” *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)). The Supreme Court has affirmed this requirement in its *KSR v. Teleflex* decision: “[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The court in *Kotzab* held that “more than a mere scintilla of evidence is necessary” to support an Examiner’s *prima facie* case. *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). This underscores the requirement for *some* evidence in making a *prima facie* case; rejections based on *no* evidence have repeatedly been reversed by the Federal Circuit. See *In re McNeil-PPC*, 2008-1546, slip op. 1, 10 (Fed. Cir. July 31, 2009) (anticipation rejection reversed where findings by the BPAI about the disclosures of a prior art patent application are not supported by substantial evidence), *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (obviousness rejection reversed where there was no finding as to the specific understanding or principle needed to support Examiner’s *prima facie* case), and *In*

re Robert Skvorecz, 2008-1221, slip op. 1, 7 (Fed. Cir. September 3, 2009) (anticipation rejection reversed where Examiner's assertion that reference contained identical recitations as the claim was unsupported by any evidence).

1. What a Reference "Teaches" Is a Question of Fact

What a reference "teaches" is a question of fact.^{3,4,5} Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁶ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);⁷ *In re Kotzab*, 217 F.3d

³ *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

⁴ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

⁵ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

⁶ In *McNeil*, the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).⁸ Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁹ Thus, when a party to a matter asserts that a reference

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁷ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

⁸ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board’s decision, adopting the Examiner’s premise, lacks the necessary substantial evidence to support a rejection of Kotzab’s claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board’s implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans’ disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁹ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court’s holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a

“teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{10,11,12,13}

claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**”) (emphasis added)

¹⁰ *See Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

¹¹ *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

¹² *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

¹³ *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

2. MPEP Standards for Determining Anticipation

An examiner bears the initial burden of factually supporting any *prima facie* conclusion of anticipation. *Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1986); *In Re King*, 801 F.2d 1324, 231 U.S.P.Q. (BNA) 136 (Fed. Cir. 1986); MPEP § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability....”). Failure of an examiner to meet this burden entitles an applicant to a patent. *Id.* (“[i]f examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent”).

The MPEP indicates that in order for an examiner to establish a *prima facie* case of anticipation of an applicant’s claim, the examiner must first interpret the claim,¹⁴ and thereafter show that the cited prior art discloses the same elements, in the same arrangement, as the elements of the claim which the examiner asserts is anticipated. More specifically, the MPEP states that “[a] claim is anticipated *only if each and every element as set forth in the claim is found*, either expressly or inherently described, in a single prior art reference. . . . The identical invention must be shown in as complete detail as is contained in the . . . claim. . . . The elements must be arranged as required by the claim”. MPEP § 2131 (emphasis added). For example, In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). *McNeil* appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend

¹⁴ With respect to interpreting a claim at issue, the MPEP directs that, during examination — as opposed to subsequent to issue — such claim be interpreted as broadly as the claim terms would reasonably allow, in light of the specification, when read by one skilled in the art with which the claimed invention is most closely connected. MPEP § 2111.

radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar as the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

McNeil, 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009) (emphasis added).

In *In re Skvorecz*, an anticipation rejection rested on an interpretation of features of a wire stand. The claim at issue required that each wire leg of the stand have a laterally displacing offset. The BPAI admitted that in the cited reference, “Buff,” the offset in the rim was not shown to be ‘for laterally displacing each wire leg relative to said upper rim’ as required by claim 1, but nonetheless maintained the rejection. The Federal Circuit reversed for lack of evidence:

On rehearing the Board stated that Buff's wire 48 is a "transverse member" and not a wire leg, and therefore that it need not have a displacing offset. Mr. Skvorecz states, and we agree, that Buff's wire 48 is a leg of the Buff structure. The Board's contrary statement is unsupported by any evidence.

Id. at p. 8 (emphasis added).

Consequently, under the guidelines of the MPEP set forth above, if there is *any* substantial difference between the prior art cited by an examiner and an applicant's claim which the examiner asserts is rendered anticipated by the prior art, the prior art does NOT establish a *prima facie* case of anticipation and, barring other rejections, the applicant is entitled to a patent on such claim.

3. MPEP Standards for Determining Obviousness

"[T]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness."¹⁵ MPEP § 2142. The MPEP indicates that in order for an examiner to establish a *prima facie* case that an invention, as defined by a claim at issue, is obvious, the examiner must (1) interpret the claim at issue; (2) define one or more prior art reference components relevant to the claim at issue; (3) ascertain the differences between the one or more prior art reference components and the elements of the claim at issue; and (4) adduce objective evidence which establishes, under a preponderance of the evidence standard, a teaching to modify the teachings of the prior art reference components such that the prior art reference components can be used to construct a device substantially equivalent to the claim at issue. This last step generally encompasses two sub-steps: (1) adducement of objective evidence teaching how to modify the prior art components to achieve the individual elements of the claim at issue; and (2) adducement of objective evidence teaching how to combine the modified

¹⁵ An invention, as embodied in the claims, is rendered obvious if an Examiner concludes that although the claimed invention is not identically disclosed or described in a reference, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. MPEP § 2141 (citing 35 U.S.C. § 103).

individual components such that the claim at issue, as a whole, is achieved. *MPEP* § 2141; *MPEP* § 2143. Each of these foregoing elements is further defined within the *MPEP*. *Id.*

This requirement has been explained recently by the Supreme Court in *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 (2007) which noted that such a rejection requires “some articulated reasoning ... to support the legal conclusion of obviousness.” As stated by the Court, obviousness can be established where “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, ***this analysis should be made explicit.***” (emphasis added). See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’).” *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741.

As further described by the Court “[A] ***patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.*** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741.

a) Interpreting a Claim at Issue

With respect to interpreting a claim at issue, the *MPEP* directs that, during examination — as opposed to subsequent to issue — the pending claims must be “given their broadest reasonable interpretation consistent with the specification.” *MPEP* § 2111. The Federal Circuit’s *en banc* decision in *Phillips v. AWH Corp.*,

415 F.3d 1303 (Fed. Cir. 2005) expressly recognized that the USPTO employs the “broadest reasonable interpretation consistent with the specification” standard:

The [PTO] determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction “in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must “conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” 37 CFR 1.75(d)(1).

Phillips at 1316. See also *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) and MPEP § 2111.

In addition, it is the PTO’s responsibility to interpret the claims during prosecution. See *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997) (the “PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.”). See also Examination Guidelines For Determining Obviousness Under 35 U.S.C. § 103: MPEP § 2141, II, A.: “The scope of the claimed invention must be clearly determined by giving the claims the ‘broadest reasonable interpretation consistent with the specification.’ See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § 2111.”

b) Definition of One or More Prior Art Reference Components Relevant to the Claim at Issue

Once the claim at issue has been properly interpreted, the next step is the definition of one or more prior art reference components (*e.g.*, electrical, mechanical, or other components set forth in a prior art reference) relevant to the

properly interpreted claim at issue. With respect to the definition of one or more prior art reference components relevant to the claim at issue, the MPEP defines three proper sources of such prior art reference components, with the further requirement that each such source must have been extant at the time of invention to be considered relevant. These three sources are as follows: patents as defined by 35 U.S.C. § 102, printed publications as defined by 35 U.S.C. § 102, and information (*e.g.*, scientific principles) deemed to be "well known in the art"¹⁶ as defined under 35 U.S.C. § 102. *MPEP* § 2141; *MPEP* § 2144.

**c) Ascertainment of Differences between Prior Art
Reference Components and Claim at Issue;
Teaching to Modify and/or Combine Prior Art
Reference Components to Remedy Those
Differences in Order to Achieve Recitations of
Claim at Issue**

With one or more prior art components so defined and drawn from the proper prior art sources, the differences between the one or more prior art reference components and the elements of the claim at issue are to be ascertained. Thereafter, in order to establish a case of *prima facie* obviousness, an examiner must set forth a rationale, supported by objective evidence¹⁷ sufficient to demonstrate under a preponderance of the evidence standard, that in the prior art extant at the time of invention there was a teaching to modify and/or combine the one or more prior art

¹⁶ The fact that information deemed to be "well known in the art" can serve as a proper source of prior art reference components seems to open the door to subjectivity, but such is not the case. As a remedy to this potential problem, *MPEP* § 2144.03 states that if an Examiner asserts that his position is derived from and/or is supported by a teaching or suggestion that is alleged to have been "well known in the art," and that if an applicant traverses such an assertion (that something was "well known within the art"), the Examiner must cite a reference in support of his or her position. The same *MPEP* section also states that when a rejection is based on facts within the personal knowledge of an Examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the Examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. *Id.* Thus, all sources of prior art reference components must be objectively verifiable.

¹⁷ The proper sources of the objective evidence supporting the rationale are the defined proper sources of prior art reference components, discussed above, with the addition of factually similar legal precedent. *MPEP* § 2144.

reference components to construct a device practicably equivalent to the claim at issue.

In *Kotzab*, insofar as the cited Evans reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its contention that “one system” is equal to “one sensor,” the Federal Circuit reversed the rejection for lack of “necessary substantial evidence to support a rejection,” stating as follows:

The Examiner cites Evans for teaching that “one system constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one sensor to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (emphasis added).

The preferable evidence relied upon is an express teaching to modify/combine within the properly defined objectively verifiable sources of prior art. In the absence of such express teaching, an examiner may attempt to establish a rationale to support a finding of such teaching reasoned from, or based upon, express teachings taken from the defined proper sources of such evidence

(i.e., properly defined objectively verifiable sources of prior art). *MPEP* § 2144; *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

The MPEP recognizes the pitfalls associated with the tendency to subconsciously use impermissible “hindsight” when an examiner attempts to establish such a rationale. The MPEP has set forth at least two rules to ensure against the likelihood of such impermissible use of hindsight. The first rule is that:

under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information,¹⁸ the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of an Applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search, and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon an Applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

MPEP § 2142 (emphasis added). Thus, if the only objective evidence of such teaching to modify and/or combine prior art reference components is an applicant’s disclosure, no evidence of such teaching exists.¹⁹

The second rule is that if an examiner attempts to rely on some advantage or expected beneficial result that would have been produced by a modification and/or combination of the prior art reference components as evidence to support a rationale to establish such teachings to modify and/or combine prior art reference components, the MPEP requires that such advantage or expected beneficial result

¹⁸ “Factual information” is information actually existing or occurring, as distinguished from mere supposition or opinion. *Black’s Law Dictionary* 532 (5th ed. 1979).

¹⁹ An applicant may argue that an Examiner’s conclusion of obviousness is based on improper hindsight reasoning. However, “[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.” *MPEP* § 2145(X)(A) (emphasis added).

be objectively verifiable teachings present in the acceptable sources of prior art (or drawn from a convincing line of reasoning based on objectively verifiable established scientific principles or teachings). *MPEP* § 2144. Thus, as a guide to avoid the use of impermissible hindsight, these rules from the *MPEP* make clear that absent some objective evidence, sufficient to persuade under a preponderance of the evidence standard, no teaching of such modification and/or combination exists.²⁰

B. Technical Material Cited by the USPTO Does Not Show/Suggest Recitations of Independent Claim 42 and Dependent Claims 2-41 and 100 as Presented Herein; Notice of Allowance of Same Respectfully Requested

²⁰ *In Re Sang Su Lee* 277 F.3d 1338 (Fed. Cir. 2002) (“When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.”) *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001) (“the central question is whether there is reason to combine [the] references,” a question of fact drawing on the *Graham* factors). “The factual inquiry whether to combine references must be thorough and searching.” *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 U.S.P.Q.2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’”) (quoting *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)); *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (“teachings of references can be combined only if there is some suggestion or incentive to do so.”) (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)). The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (“even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.”)).

1. Independent Claim 1

Independent Claim 1 recites as follows:

1. A system, comprising:

[a] a body portion;

[b] an extending part with a proximal end piece and one or more distal end pieces and wherein the proximal end piece is coupled to the body portion, the one or more distal end pieces are configured to insert into an animal, and the one or more distal end pieces are configured to controllably telescopically extend from the proximal end piece;

[c] at least one receiving body in communication with the extending part;

[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend; and

[e] a control circuit coupled to the receiving body and/or the extending part.²¹

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference “teaches” at least some of the text of Independent Claim 1, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Independent Claim 1. Moreover, Applicant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render its components unfit for their intended purpose.

²¹ The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

a) The USPTO-Cited Technical Material Fails to Recite Several Express Terms of Independent Claim 1 and Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

Concerning this, the USPTO has recently stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 33-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, pp. 2-3 (29 October 2009) (emphasis added).²²

As set forth above, Independent Claim 1 recites as follows: “A system, comprising: [a] a body portion; [b] an extending part with a proximal end piece

²² Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant’s claims, but appears to have not addressed the express language of both Applicant’s claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

and one or more distal end pieces and wherein the proximal end piece is coupled to the body portion, the one or more distal end pieces are configured to insert into an animal, and the one or more distal end pieces are configured to controllably telescopically extend from the proximal end piece; [c] at least one receiving body in communication with the extending part; [d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend; and [e] a control circuit coupled to the receiving body and/or the extending part.”²³

It appears to Applicant that the USPTO has mapped “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” onto a configuration by which “*see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34.*” Applicant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO’s burden (e.g., such as by examples drawn from Applicant’s claims or detailed description),²⁴ and furthermore, Applicant points out that this mapping does not address at least the “wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend.”

In view of the foregoing, Applicant points out that although Independent Claim 1 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited material fails to recite at

²³ The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

²⁴ Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 (“A practitioner should represent a client zealously within the bounds of the law.”); 37 C.F.R. § 10.84 (“[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part.”); and 37 C.F.R. § 10.76 (“A practitioner should represent a client competently.”). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO’s behalf.

least the foregoing bolded recitations of Independent Claim 1,²⁵ under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Independent Claim 1. For these reasons, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

b) The USPTO is Characterizing/Asserting U.S. Pat. No. 6,385,472 (“Hall”) to “Teach” the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part

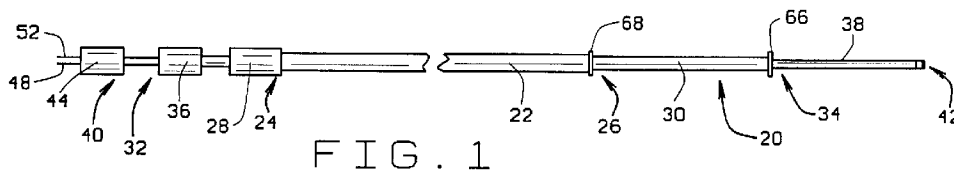
²⁵ Although Independent Claim 42 has been quoted in the present rejection, several claim terms have not been addressed in its analysis, as shown below.

comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 26-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

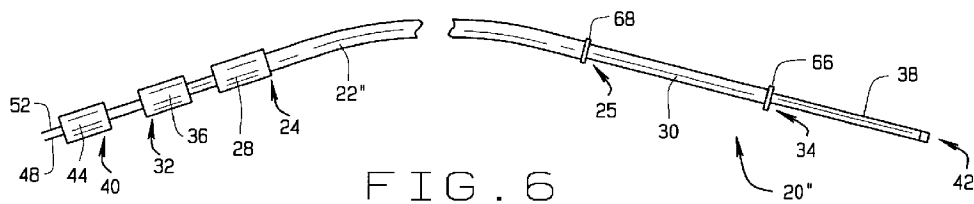
Office Action, p. 2-3 (29 October 2009). Applicant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Hall “Teaches” Recitations of Independent Claim 1

Applicant respectfully points out that Applicant has reviewed the Hall reference identified by the USPTO, and so far as Applicant can discern, the Hall reference does not recite “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” as recited in Applicant's Independent Claim 1. Rather, the textual portions of Hall cited by the USPTO actually recite as follows:



Hall Fig. 1



Hall Fig. 6

nostic or therapeutic agents. FIG. 9 shows such a catheter **20'** with a central passage **21** for the delivery of diagnostic or therapeutic agents. 35

Hall at col. 3, lines 33-35.

target location. It would also be possible to automate the process, allowing the surgeon to input either a desired direction or location, and using a computer to control the magnetic field and the telescoping of the sleeve and the extension member. 30

Hall at col. 5, lines 30-34.

65 The movement of the sheath, the extension member, and even the stylette, can be automated and operated by motor instead of manually, if desired.

Hall at col. 6, lines 65-67.

25 The catheter can be provided with one or more electrodes for cardiac mapping, pacing, or ablation. Alternatively, the catheter can be used in some other procedure such as the delivery of therapeutic agents.

Hall at col. 2, lines 25-28.

The USPTO is characterizing Hall to “teach” at least some of the text of Independent Claim 1, but does not support its characterization with objectively

verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference “teaches” is a question of fact.^{26,27,28} Conclusory statements that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);²⁹ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);³⁰ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed.

²⁶ *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board’s characterization of the disclosure in the FPR Publication for **substantial evidence**.”) (emphasis added).

²⁷ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”)

²⁸ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

²⁹ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki’s tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board’s determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

³⁰ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s

Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).³¹ Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.³²

handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

³¹ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board’s decision, adopting the Examiner’s premise, lacks the necessary substantial evidence to support a rejection of Kotzab’s claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board’s implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans’ disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

³² *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court’s holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert’s conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference.

Thus, when a party to a matter asserts that a reference “teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{33,34,35,36} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.” (emphasis added)

³³ See *Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

³⁴ See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).1993) (reversing PTO and holding, when PTO presented no evidence to cure prima facie differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”).

³⁵ See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

³⁶ See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

As can be seen from the foregoing, for example, the USPTO-identified portions of Hall do not recite the text of at least Clause [d] of Independent Claim 1: “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend.” Instead, Hall indicates “For example, in the alternate construction shown in FIG. 5, the distal end 42 of the extension member 38 can be provided with two electrodes 60 and 62, separated and electrically insulated from each other by a generally diametrically extending partition 64” (Hall col. 4, lines 26-31).

Applicant has shown by direct quotations that Independent Claim 1 and the Hall reference are very different on their faces. *See supra* at p. 37 (quotation of Claim 1); and at p. 41 *et seq.* (quotation of Hall). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 1, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Hall does not recite the text of at least Clause [d] of Applicant’s Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Hall could be modified/combined to teach at least Clause [d] of Independent Claim 1, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of Hall, Applicant demonstrated above that the express recitations of Hall are not as the

USPTO alleges, and that the USPTO has provided no evidence—let alone the preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what Hall “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, the USPTO has presented no evidence that Hall teach as asserted by the USPTO. In addition, Applicant respectfully points out that even if the USPTO’s assertions regarding the teachings of Hall were supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of Hall to the actual express language of Applicant’s Independent Claim 1. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

**(2) The USPTO
Characterization/Assertion
Appears to be Based on
Inadvertent Impermissible
Hindsight, Personal Knowledge, or
Official Notice; Applicant
Requests Issuance of Notice of
Allowability**

Given that Applicant has shown, above, what Hall actually recite, the question thus naturally arises as to how the USPTO saw Hall as “teaching” something related to Clause [d] of Independent Claim 1. Applicant respectfully points out that the Applicant’s Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of Hall as set forth, it follows that the USPTO is interpreting Hall through the lens of Applicant’s application, which is impermissible hindsight use. Thus, at present, the USPTO’s assertions regarding Hall are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie*

case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO “teaches,” Applicant infers that the USPTO is relying on “personal knowledge” and/or is taking “official notice” of one or more factors to reach the factual conclusion of what the cited technical material “teaches.” In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting forth objectively verifiable evidence in support of the USPTO’s currently unsupported assertions regarding what the cited technical material “teaches” and/or should be interpreted to “teach.” *See, e.g.,* MPEP § 2144.03(C), *If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

- c) **The USPTO-Suggested Modifications/Combinations to Meet the Recitations of Independent Claim 1 Are a “Mere Conclusory Statement” Without Evidentiary Support/Change the Principle of Operation of Components of Cited References/Render Such Components Unfit for Intended Purpose; No Teaching to Combine/Modify Components as a Matter of Law.**

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions

regarding alleged teaching to modify/combine Hall to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that (1) the USPTO's assertions regarding a teaching to modify/combine the technologies of Hall appear to be based on conclusory statement(s) without evidentiary support, (2) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of one or more of the technologies; and (3) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall as suggested by the USPTO in that such combination will render one or more of the technologies unfit for their intended purposes.

**(1) The USPTO Assertions Regarding
A Teaching to Modify/Combine to
Meet the Recitations of
Independent Claim 1 Are Based on
“Mere Conclusory Statements”
Without Evidentiary Support**

As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's “*analysis should be made explicit*” ... [*and* that] rejections ... *cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

Concerning Claim 1, as noted above, the USPTO has stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize the Hall reference. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a “mere conclusory statement[.]” Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

(2) The USPTO-Suggested Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In *re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.).

As noted above, the USPTO has stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

Applicant respectfully asserts that one reason for Hall's lack of disclosure of “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” may be gleaned from principles of operation indicated in this recitation:

For example, in the alternate construction shown in FIG. 5, the distal end 42 of the extension member 38 can be provided with two electrodes 60 and 62, separated and electrically insulated from each other by a generally diametrically extending partition 64.

Hall at col. 6, lines 26-31(emphasis added).

Applicant respectfully points out that were one to incorporate the two sensors as taught by instant invention into the structure of Hall, Hall would no longer have “electrodes 60 and 62, separated and electrically insulated from each other by a generally diametrically extending partition 64.” Thus, the USPTO-suggested modifications/combinations would change the principle of operation of Hall for at least this reason.

As discussed above, one reason why such modified Hall technologies would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to incorporate the Hall technologies to provide “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend,” as recited in Independent Claim 1. Hence, in addition to the USPTO-suggested modification/combination, there would need to be some type of reconstruction and/or redesign – appropriate to the capabilities of the structure and method of Hall – to provide for the structure of the instant invention.

As has been shown above, the technologies of Hall modified/combined as suggested by the USPTO would require “substantial reconstruction and redesign of the elements shown in [... Hall] as well as a change in the basic principle under which the [... Hall] construction was designed to operate” in order to render the USPTO-suggested combination capable of performing even a subset of the intended purposes of the technologies of Hall.³⁷ As has also been shown, even if the USPTO-suggested combination were to be somehow hypothetically modified such that the USPTO suggested modification/combination became somewhat workable, such a hypothetically modified version of the USPTO-suggested combination would itself require “substantial reconstruction and redesign of the [hypothetically modified] elements shown in [... Hall] as well as a change in the basic principle

³⁷ This statement reflects Applicant’s current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Hall’s intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

under which the [hypothetically modified] [... Hall] construction was designed to operate” in order to perform the intended communications. Accordingly, insofar as that the USPTO-suggested modification itself would likely require at least one additional and as-yet-hypothetical modifications as explained above, under the MPEP standards set forth in block quote above, the USPTO’s suggested modification/combination “would change the principle of operation” of Hall’s technologies.

Insofar as that the USPTO-suggested modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render the USPTO-suggested modification/combination capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Hall will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such references to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Independent Claim 1 patentable and issue a Notice of Allowance of Applicant’s Independent Claim 1 for at least the foregoing reasons.

2. Dependent Claims 2-41 and 100 Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-41 and 100³⁸ depend either directly or indirectly from Independent Claim 1. “A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.” *See* 35

³⁸ In relation to these dependent claims, the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of its assertions regarding what the USPTO-cited material “discloses.” Insofar as this alleged disclosure is not literally recited in such material, Applicant respectfully asserts that the Examiner must have relied on “personal knowledge” or taken improper “official notice” of one or more factors to reach each of these assertions. Applicant accordingly requests an appropriate affidavit or declaration in support of any of these rejections that are to be maintained, including any considerations purported to reflect what is “well known in the art.” *See, e.g.*, 37 C.F.R. 1.104(d)(2).

U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-41 and 100 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that the USPTO hold Dependent Claims 2-41 and 100 patentable for at least the foregoing reasons, and issue a Notice of Allowability on same.

3. Dependent Claim 2 is Independently Patentable

Independent Claim 1 recites as follows:

A system, comprising:

[a] a body portion;

[b] an extending part with a proximal end piece and one or more distal end pieces and wherein the proximal end piece is coupled to the body portion, the one or more distal end pieces are configured to insert into an animal, and the one or more distal end pieces are configured to controllably telescopically extend from the proximal end piece;

[c] at least one receiving body in communication with the extending part;

[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend; and

[e] a control circuit coupled to the receiving body and/or the extending part.³⁹

Dependent Claim 2 has been amended as follows:

2. The system of Claim 1, [f] wherein two or more distal end pieces each comprise:

³⁹ The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

[g] a porthole which is opened or closed to selectively provide communication from the exterior of each distal end piece to within the extended part or main body and to retract and deploy the sensor.⁴⁰

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference “teaches” at least some of the text of Dependent Claim 2, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Dependent Claim 2. Moreover, Applicant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render its components unfit for their intended purpose.

Concerning this subject matter, the USPTO has stated the following:

As to Applicant's arguments with respect to Claim 1 and 2:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part

⁴⁰ The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 26-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action at p. 2-3 (29 October 2009). Applicant disagrees and traverses the rejection on several grounds.⁴¹

First, the USPTO-cited material fails to recite several express terms of Dependent Claim 2 and therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 2. It appears to Applicant that the USPTO has mapped “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” onto a configuration by which “see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34.” Applicant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO’s burden (e.g., such as by examples drawn from Applicant’s claims or detailed description),⁴² and furthermore, Applicant points out that this mapping does not address at least the “wherein the

⁴¹ Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant’s claims, and has not addressed the express language of both Applicant’s claims and the cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

⁴² Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. See, e.g., 37 C.F.R. § 10.83 (“A practitioner should represent a client zealously within the bounds of the law.”); 37 C.F.R. § 10.84 (“[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part.”); and 37 C.F.R. § 10.76 (“A practitioner should represent a client competently.”). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO’s behalf.

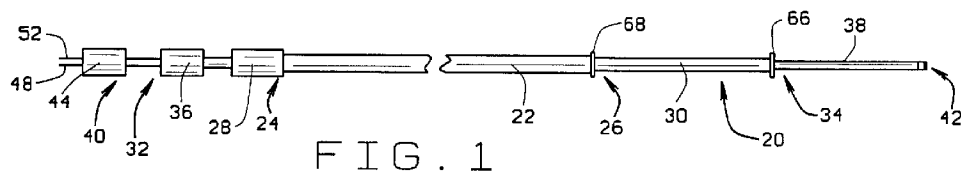
sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend.”

It also appears to Applicant that the USPTO has mapped “[g] a porthole which is opened or closed to selectively provide communication from the exterior of each distal end piece to within the extended part or main body and arranged through which to retract and deploy the sensor” onto “*see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34.*” Applicant notes that the USPTO has not explained how it reaches this mapping under the broadest reasonable interpretation framework as is the USPTO’s burden, and furthermore, Applicant points out that this mapping does not address at least the “porthole” (of Dependent Claim 2 as amended).

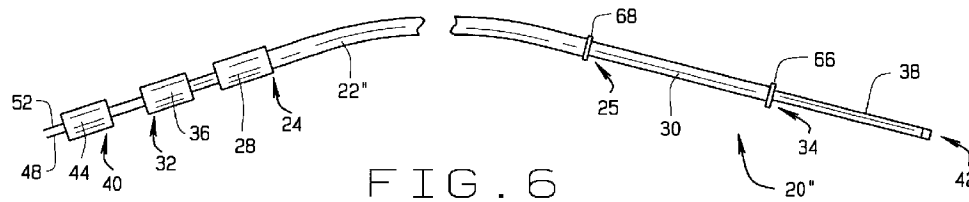
In view of the foregoing, Applicant points out that although Dependent Claim 2 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited technical material fails to recite at least the foregoing bolded recitations of Dependent Claim 2,⁴³ under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Dependent Claim 2. For these reasons, Applicant respectfully asks the USPTO to hold Dependent Claim 2 allowable and to issue a Notice of Allowability of same.

Until the USPTO has supported its statement under the broadest reasonable interpretation framework, moreover, Applicant here returns to the express language of the claim. Applicant has reviewed the material identified by the USPTO, and so far as Applicant can discern, the Hall reference does not recite “a porthole which is opened or closed to selectively provide communication.” Rather, the textual portions of Hall cited by the USPTO actually recite as follows:

⁴³ Although Dependent Claim 43 has been quoted in the present rejection, several claim terms have not been addressed in its analysis, as shown below.



Hall Fig. 1



Hall Fig. 6

nostic or therapeutic agents. FIG. 9 shows such a catheter **20'** with a central passage **21** for the delivery of diagnostic or therapeutic agents.

Hall at col. 3, lines 33-35.

target location. It would also be possible to automate the process, allowing the surgeon to input either a desired direction or location, and using a computer to control the magnetic field and the telescoping of the sleeve and the extension member.

Hall at col. 5, lines 30-34.

The movement of the sheath, the extension member, and even the stylette, can be automated and operated by motor instead of manually, if desired.

Hall at col. 6, lines 65-67.

The catheter can be provided with one or more electrodes for cardiac mapping, pacing, or ablation. Alternatively, the catheter can be used in some other procedure such as the delivery of therapeutic agents.

Hall at col. 2, lines 25-28.

The USPTO is characterizing Hall to “teach” the text of Dependent Claim 2, but does not support its characterization with objectively verifiable evidence, therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 2. What a reference “teaches” is a question of fact.^{44,45,46} Conclusory statements that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁴⁷ *In re Lee*, 277 F.3d 1338 (Fed. Cir.

⁴⁴ *See Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence.”) (emphasis added).

⁴⁵ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”)

⁴⁶ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

⁴⁷ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

2002);⁴⁸ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).⁴⁹ Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁵⁰ Thus, when a

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁴⁸ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

⁴⁹ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board’s decision, adopting the Examiner’s premise, lacks the necessary substantial evidence to support a rejection of Kotzab’s claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board’s implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans’ disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁵⁰ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court’s holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient

party to a matter asserts that a reference “teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{51,52,53,54} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit

clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**”) (emphasis added)

⁵¹ *See Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

⁵² *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

⁵³ *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

⁵⁴ *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Hall do not recite the text of at least Clause [g] of Dependent Claim 2: “a porthole which is opened or closed to selectively provide communication.” Instead, Hall indicates “For example, in the alternate construction shown in FIG. 5, the distal end 42 of the extension member 38 can be provided with two electrodes 60 and 62, separated and electrically insulated from each other by a generally diametrically extending partition 64” (Hall at col. 6, lines 26-31) (emphasis added).

Applicant has shown by direct quotations that Dependent Claim 2 and the USPTO’s citations are very different on their faces. *See supra* at p. 67 (quotation of Claim 2 with its parent claim); and at p. 58 *et seq.* (quotation of Hall). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 2, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 2 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Hall does not recite the text of at least Clause [g] of Applicant’s Dependent Claim 2, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Hall could be modified/combined to teach at least Clause [g] of Dependent Claim 2, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 2 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Dependent Claim 2 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of the cited material, Applicant demonstrated above that the express recitations of the cited material are not as the USPTO alleges, and that the USPTO has provided no evidence—let alone the preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what the cited material “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, the USPTO has presented no evidence that the cited material teaches as asserted by the USPTO. In addition, Applicant respectfully points out that even if the USPTO’s assertions regarding the teachings of the cited material were supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of the cited material to the actual express language of Applicant’s Dependent Claim 2. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 2 allowable and issue a Notice of Allowability of same.

Given that Applicant has shown, above, what the cited material actually recites, the question thus naturally arises as to how the USPTO saw the cited material as “teaching” something related to Clause [g] of Dependent Claim 2. Applicant respectfully points out that the Applicant’s Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of the cited material as set forth, it follows that the USPTO is interpreting the cited material through the lens of Applicant’s application, which is impermissible hindsight use. Thus, at present, the USPTO’s assertions regarding the cited material are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant

respectfully requests that the USPTO hold Dependent Claim 2 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO “teaches,” Applicant infers that the USPTO is relying on “personal knowledge” and/or is taking “official notice” of one or more factors to reach the factual conclusion of what the cited technical material “teaches.” In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting forth objectively verifiable evidence in support of the USPTO’s currently unsupported assertions regarding what the cited technical material “teaches” and/or should be interpreted to “teach.” *See, e.g., MPEP § 2144.03(C), If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

Furthermore, the USPTO-suggested modifications/combinations to meet the recitations of dependent claim 2 are a “mere conclusory statement” without evidentiary support. As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO’s “*analysis should be made explicit*” ... [*and that*] rejections ... *cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

As noted above, the USPTO has recently stated the following:

As to Applicant's arguments with respect to Claim 1:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action at p. 2-3 (29 October 2009).

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize the Hall reference. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a “mere conclusory statement[.]” Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

4. Dependent Claim 15 is Independently Patentable

Independent Claim 1 recites as follows:

A system, comprising:

- [a] a body portion;
- [b] an extending part with a proximal end piece and one or more distal end pieces and wherein the proximal end piece is coupled to the body portion, the one or more distal end pieces are configured to insert into an animal, and the one or more distal end pieces are configured to controllably telescopically extend from the proximal end piece;
- [c] at least one receiving body in communication with the extending part;
- [d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend; and
- [e] a control circuit coupled to the receiving body and/or the extending part.

Dependent Claim 15 recites as follows:

15. The system of Claim 1, [f] wherein the extending part comprises:

[g] a polymer that converts one form of energy to a new form of energy operative for moving fluid through the extending part.

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference “teaches” at least some of the text of Dependent Claim 15, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Dependent Claim 15. Moreover, Applicant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render its components unfit for their intended purpose.

Concerning this subject matter, the USPTO has stated the following:

As to Applicant's arguments with respect to Claim 1:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p.2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 15:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009). Applicant disagrees and traverses the rejection on several grounds.⁵⁵

⁵⁵ Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, and has not addressed the express language of both Applicant's claims and the

First, the USPTO-cited material fails to recite several express terms of Dependent Claim 15 and therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 15. It appears to Applicant that the USPTO has mapped “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” onto a configuration by which “*see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34.*” Applicant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO’s burden (e.g., such as by examples drawn from Applicant’s claims or detailed description),⁵⁶ and furthermore, Applicant points out that this mapping does not address at least the “wherein each distal end piece includes a sensor.”

It also appears to Applicant that the USPTO has mapped “**providing a polymer coupled to the flexible finger operative for converting one form of energy to a new form of energy and moving fluid through the extending part**” onto “*electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location.*” Applicant notes that the USPTO has not explained how it reaches this mapping under the broadest reasonable interpretation framework as is the USPTO’s burden, and furthermore, Applicant points out that this mapping does not address at

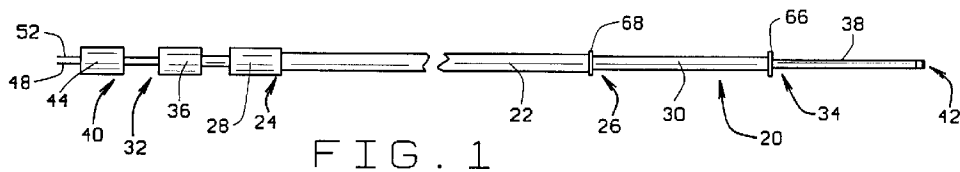
cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

⁵⁶ Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 (“A practitioner should represent a client zealously within the bounds of the law.”); 37 C.F.R. § 10.84 (“[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part.”); and 37 C.F.R. § 10.76 (“A practitioner should represent a client competently.”). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO’s behalf.

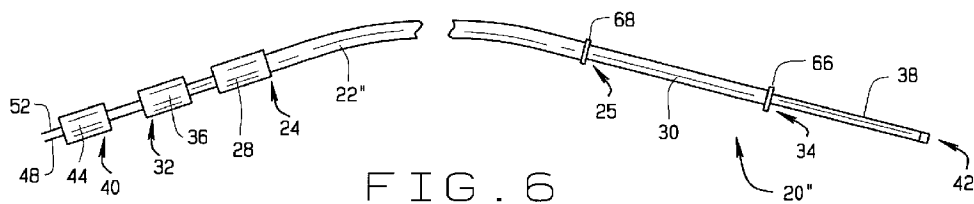
least the “**moving fluid through the extending part**” (of Dependent Claim 15 as amended).

In view of the foregoing, Applicant points out that although Dependent Claim 15 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited technical material fails to recite at least the foregoing bolded recitations of Dependent Claim 15, under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Dependent Claim 15. For these reasons, Applicant respectfully asks the USPTO to hold Dependent Claim 15 allowable and to issue a Notice of Allowability of same.

Until the USPTO has supported its statement under the broadest reasonable interpretation framework, moreover, Applicant here returns to the express language of the claim. Applicant has reviewed the material identified by the USPTO, and so far as Applicant can discern, the Hall reference does not recite a “moving fluid through the extending part.” Rather, the textual portions of Hall cited by the USPTO for the rejection of Independent Claim 1 actually recite as follows:



Hall Fig. 1



Hall Fig. 6

nostic or therapeutic agents. FIG. 9 shows such a catheter 20' with a central passage 21 for the delivery of diagnostic or therapeutic agents. 35

Hall at col. 3, lines 33-35.

target location. It would also be possible to automate the process, allowing the surgeon to input either a desired direction or location, and using a computer to control the magnetic field and the telescoping of the sleeve and the extension member. 30

Hall at col. 5, lines 30-34.

65 The movement of the sheath, the extension member, and even the stylette, can be automated and operated by motor instead of manually, if desired.

Hall at col. 6, lines 65-67.

25 The catheter can be provided with one or more electrodes for cardiac mapping, pacing, or ablation. Alternatively, the catheter can be used in some other procedure such as the delivery of therapeutic agents.

Hall at col. 2, lines 25-28.

The USPTO is characterizing Hall to “teach” the text of Dependent Claim 15, but does not support its characterization with objectively verifiable evidence, therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 15. What a reference “teaches” is a question of fact.^{57,58,59} Conclusory statements that a reference “teaches” something beyond

⁵⁷ See *Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board’s **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.”) (emphasis added).

⁵⁸ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”)

its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁶⁰ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);⁶¹ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).⁶² Even if the PTO personnel were to seek to support their

⁵⁹ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

⁶⁰ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki’s tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board’s determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁶¹ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

⁶² In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁶³ Thus, when a party to a matter asserts that a reference “teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁶³ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.”) (emphasis added)

what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{64,65,66,67} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Hall do *not recite* the text of at least Clause [g] of Dependent Claim 15: “moving fluid through the extending part.” Instead, Hall indicates “There is also at least one magnet, and preferably more than one magnet, on the distal end portion of the extension member to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field” (Hall Abstract). To Applicant, it appears that the USPTO has tried to close a significant gap between these actual recitations of the Hall reference and the structure of the “wherein the sensors are arranged to change a distance between at least two of the

⁶⁴ See *Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

⁶⁵ See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

⁶⁶ See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

⁶⁷ See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

sensors as the one or more distal end pieces telescopically extend” and “moving fluid through the extending part” (of Applicant’s Claim 15) without providing any evidence, by merely making this unsupported assertion.

Applicant has shown by direct quotations that Dependent Claim 15 and the USPTO’s citations are very different on their faces. *See supra* at p. 67 (quotation of Claim 15 with its parent claim); and at p. 70 *et seq.* (quotation of Hall). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 15, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 15 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Hall does not recite the text of at least Clause [g] of Applicant’s Dependent Claim 15, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Hall could be modified/combined to teach at least Clause [g] of Dependent Claim 15, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 15 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Dependent Claim 15 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of the cited material, Applicant demonstrated above that the express recitations of the cited material are not as the USPTO alleges, and that the USPTO has provided no evidence—let alone the preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what the cited material “teaches.” Accordingly, Applicant respectfully points out that in view of the

foregoing, the USPTO has presented no evidence that the cited material teaches as asserted by the USPTO. In addition, Applicant respectfully points out that even if the USPTO's assertions regarding the teachings of the cited material were supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of the cited material to the actual express language of Applicant's Dependent Claim 15. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 15 allowable and issue a Notice of Allowability of same.

Given that Applicant has shown, above, what the cited material actually recites, the question thus naturally arises as to how the USPTO saw the cited material as "teaching" something related to Clause [g] of Dependent Claim 15. Applicant respectfully points out that the Applicant's Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of the cited material as set forth, it follows that the USPTO is interpreting the cited material through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, the USPTO's assertions regarding the cited material are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 15 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO "teaches," Applicant infers that the USPTO is relying on "personal knowledge" and/or is taking "official notice" of one or more factors to reach the factual conclusion of

what the cited technical material “teaches.” In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting forth objectively verifiable evidence in support of the USPTO’s currently unsupported assertions regarding what the cited technical material “teaches” and/or should be interpreted to “teach.” *See, e.g.,* MPEP § 2144.03(C), *If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

As noted above, the USPTO has stated as follows:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to concert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

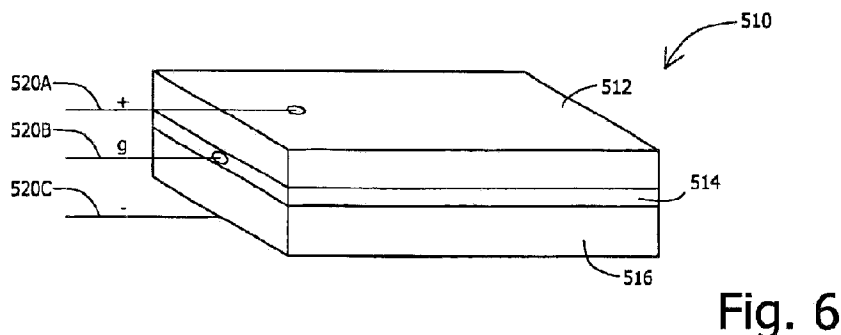
Office Action, p. 5 (29 October 2009).

Although the USPTO states “Iddan teaches electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location,” Applicant has pointed out above that the USPTO has not engaged in the broadest reasonable interpretation framework regarding Clause [g], and accordingly has not addressed at least the “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” recitations of Clause [d]. Accordingly, until the USPTO has supported its statement under the broadest reasonable interpretation framework Applicant here returns to the express language of the claim and thus respectfully points out that Applicant has reviewed the Iddan reference identified by the USPTO, and so far as Applicant can discern, the Iddan

reference does not recite “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” as recited in Applicant's Independent Claim 1. Rather, the USPTO has not provided a citation as to where the alleged teaching “electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location” might be found. Iddan discloses:

In operation, when positive voltage is applied to positive conductor 520A and first piezo material 512, the first piezo material 512 expands. When negative voltage is applied to negative conductor 520C and second piezo material 512 contracts. As a result of current being applied to conductors 520A and 520C, the piezo element 510 bends, creating a radius of curvature.

Iddan at col. 14, lines 10-16.



Iddan Fig. 6.

Additionally, the USPTO is characterizing Iddan to “teach” at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence, therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference “teaches” is a question of fact.^{68,69,70} Conclusory statements that a

⁶⁸ See *Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.”) (emphasis added).

⁶⁹ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-

reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁷¹ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);⁷² *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory

to-one correspondence).1993) (reversing PTO and holding, when PTO presented no evidence to cure prima facie differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”).

⁷⁰ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

⁷¹ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” See *id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

See *id.*, 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁷² In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. See *id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

statements standing alone are not “evidence.”).⁷³ Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁷⁴ Thus, when a party to a matter asserts that a reference “teaches” something

⁷³ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board’s decision, adopting the Examiner’s premise, lacks the necessary substantial evidence to support a rejection of Kotzab’s claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board’s implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans’ disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁷⁴ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court’s holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert’s conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**”) (emphasis added)

beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{75,76,77,78} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Iddan do *not recite* the text of at least Clause [d] of Independent Claim 1: “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” and Clause [g] of Dependent Claim 15: “moving fluid

⁷⁵ See *Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

⁷⁶ See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

⁷⁷ See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

⁷⁸ See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

through the extending part.” Instead, Iddan recites “creating a radius of curvature.” Consequently, on its face, Iddan does not show the text of at least Clause [d] of Independent Claim 1 and Clause [g] of Dependent Claim 15. To Applicant, it appears that the USPTO has tried to close a significant gap between this actual recitation of the Iddan reference and the “moving fluid through the extending part” (in Clause [g] of Applicant’s Claim 15) without providing any evidence, by merely making this unsupported assertion.

Applicant has shown by direct quotations that Dependent Claim 15 and the Iddan reference are very different on their faces. *See supra* at p. 67 (quotation of Claim 15); and at p. 78 *et seq.* (quotation of Iddan). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 15, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 15 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Iddan does not recite the text of at least Clause [g] of Applicant’s Dependent Claim 15, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Iddan could be modified/combined to teach at least Clause [g] of Independent Claim 15, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 15 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Dependent Claim 15 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of Iddan, Applicant demonstrated above that the express recitations of Iddan are not as the USPTO alleges, and that the USPTO has provided no evidence—let alone the

preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what Iddan “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, the USPTO has presented no evidence that Iddan teach as asserted by the USPTO. In addition, Applicant respectfully points out that even if the USPTO’s assertions regarding the teachings of Iddan were supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of Iddan to the actual express language of Applicant’s Independent Claim 1. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

Given that Applicant has shown, above, what Iddan actually recite, the question thus naturally arises as to how the USPTO saw Iddan as “teaching” something related to Clause [g] of Dependent Claim 15. Applicant respectfully points out that the Applicant’s Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of Iddan as set forth, it follows that the USPTO is interpreting Iddan through the lens of Applicant’s application, which is impermissible hindsight use. Thus, at present, the USPTO’s assertions regarding Iddan are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 15 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO “teaches,” Applicant infers that the USPTO is relying on “personal knowledge” and/or is

taking “official notice” of one or more factors to reach the factual conclusion of what the cited technical material “teaches.” In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting forth objectively verifiable evidence in support of the USPTO’s currently unsupported assertions regarding what the cited technical material “teaches” and/or should be interpreted to “teach.” *See, e.g.,* MPEP § 2144.03(C), *If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Hall and/or Iddan to meet the recitations of Dependent Claim 15, there can be no such teaching as a matter of law. Specifically, shown following is that (1) the USPTO’s assertions regarding a teaching to modify/combine the technologies of Hall with the technologies of Iddan appear to be based on conclusory statement(s) without evidentiary support, (2) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall with the technologies of Iddan as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of one or more of the technologies; and (3) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall with the technologies of Iddan as suggested by the USPTO in that such combination will render one or more of the technologies unfit for their intended purposes.

Furthermore, the USPTO-suggested modifications/combinations to meet the recitations of dependent Claim 15 are a “mere conclusory statement” without evidentiary support. As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO’s “*analysis should*

be made explicit” ... [and that] rejections ... cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ KSR v. Teleflex, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

As noted above, the USPTO has recently stated the following:

As to Applicant's arguments with respect to Claim 1:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 26-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 15:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009).

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Hall and Iddan references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a “mere conclusory statement[.]” Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In *re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.).

As noted above, the USPTO has stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 15:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009).

Applicant respectfully asserts that one reason for Hall's lack of disclosure of "moving fluid through the extending part" may be gleaned from principles of operation indicated in this recitation:

"There is also at least one magnet, and preferably more than one magnet, on the distal end portion of the extension member to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field" (Hall Abstract) (emphasis added).

Applicant respectfully points out that were one to incorporate the piezoelectric polymers as allegedly taught by Iddan into the structure of Hall, Hall would no longer be "oriented by the application of an externally applied magnetic field." Thus, the USPTO-suggested modifications/combinations would change the principle of operation of Hall for at least this reason.

As discussed above, one reason why such modified Hall technologies would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to incorporate the structure of Iddan with the Hall technologies to provide a "moving fluid through the extending part," as recited in Dependent Claim 15. Hence, in addition to the USPTO-suggested modification/combination, there would need to be some type of reconstruction and/or redesign – appropriate to the capabilities of the structure and method of Hall – to provide for the structure of Iddan.

As has been shown above, the technologies of Hall modified/combined with the structure of Iddan as suggested by the USPTO would require "substantial reconstruction and redesign of the elements shown in [... Hall] as well as a change in the basic principle under which the [... Hall] construction was designed to operate" in order to render the USPTO-suggested combination capable of performing even a subset of the intended purposes of the technologies of Hall.⁷⁹ As

⁷⁹ This statement reflects Applicant's current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Hall's intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

has also been shown, even if the USPTO-suggested combination were to be somehow hypothetically modified such that the USPTO suggested modification/combination became somewhat workable, such a hypothetically modified version of the USPTO-suggested combination would itself require “substantial reconstruction and redesign of the [hypothetically modified] elements shown in [... Hall] as well as a change in the basic principle under which the [hypothetically modified] [...Hall] construction was designed to operate” in order to perform the intended function. Accordingly, insofar as that the USPTO-suggested modification itself would likely require at least one additional and as-yet-hypothetical modifications as explained above, under the MPEP standards set forth in block quote above, the USPTO’s suggested modification/combination “would change the principle of operation” of Hall’s technologies.

Insofar as that the USPTO-suggested modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render the USPTO-suggested modification/combination capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Hall will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such references to meet the recitations of Dependent Claim 15 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Dependent Claim 15 patentable and issue a Notice of Allowance of Applicant’s Dependent Claim 15 for at least the foregoing reasons.

5. Dependent Claim 16 is Independently Patentable

Independent Claim 1 recites as follows:

A system, comprising:

[a] a body portion;

- [b] an extending part with a proximal end piece and one or more distal end pieces and wherein the proximal end piece is coupled to the body portion, the one or more distal end pieces are configured to insert into an animal, and the one or more distal end pieces are configured to controllably telescopically extend from the proximal end piece;
- [c] at least one receiving body in communication with the extending part;
- [d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend; and
- [e] a control circuit coupled to the receiving body and/or the extending part.

Dependent Claim 16 recites as follows:

16. The method of Claim 1, [f] wherein the method further comprises:

[g] including a polymer coupled to the flexible finger operative for converting one form of energy to a new form of energy operative for providing a peristaltic wave motion for moving a fluid.

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference “teaches” at least some of the text of Dependent Claim 16, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Dependent Claim 16. Moreover, Applicant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render its components unfit for their intended purpose.

Concerning this subject matter, the USPTO has stated the following:

As to Applicant's arguments with respect to Claim 1:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 16:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009). Applicant disagrees and traverses the rejection on several grounds.⁸⁰

⁸⁰ Applicant respectfully asserts that the USPTO has apparently not examined the recitations of Applicant's claims, and has not addressed the express language of both Applicant's claims and the

First, the USPTO-cited material fails to recite several express terms of Dependent Claim 16 and therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 16. It appears to Applicant that the USPTO has mapped “[d] two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” onto a configuration by which “*see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34.*” Applicant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO’s burden (e.g., such as by examples drawn from Applicant’s claims or detailed description),⁸¹ and furthermore, Applicant points out that this mapping does not address at least the “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend.”

It also appears to Applicant that the USPTO has mapped **“including a polymer coupled to the flexible finger operative for converting one form of energy to a new form of energy operative for providing a peristaltic wave motion for moving a fluid”** onto “*electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location.*” Applicant notes that the USPTO has not explained how it reaches this mapping under the broadest reasonable interpretation framework as is

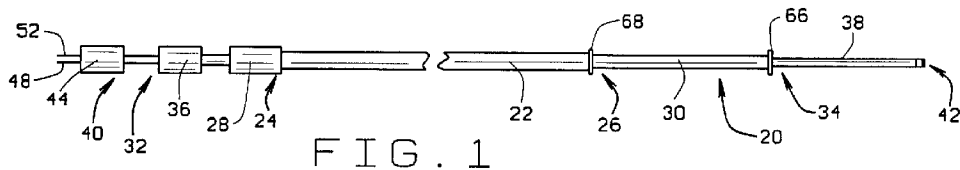
cited technical material. Accordingly, Applicant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

⁸¹ Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 (“A practitioner should represent a client zealously within the bounds of the law.”); 37 C.F.R. § 10.84 (“[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part.”); and 37 C.F.R. § 10.76 (“A practitioner should represent a client competently.”). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO’s behalf.

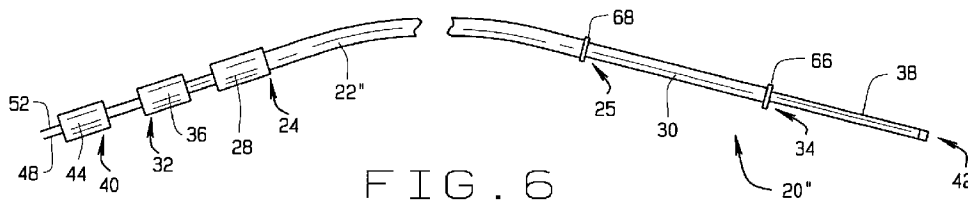
the USPTO's burden, and furthermore, Applicant points out that this mapping does not address at least the "peristaltic wave" (of Dependent Claim 16 as amended).

In view of the foregoing, Applicant points out that although Dependent Claim 16 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited technical material fails to recite at least the foregoing bolded recitations of Dependent Claim 16, under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Dependent Claim 16. For these reasons, Applicant respectfully asks the USPTO to hold Dependent Claim 16 allowable and to issue a Notice of Allowability of same.

Until the USPTO has supported its statement under the broadest reasonable interpretation framework, moreover, Applicant here returns to the express language of the claim. Applicant has reviewed the material identified by the USPTO, and so far as Applicant can discern, the Hall reference does not recite a "peristaltic wave." Rather, the textual portions of Hall cited by the USPTO for the rejection of Independent Claim 1 actually recite as follows:



Hall Fig. 1



Hall Fig. 6

nostic or therapeutic agents. FIG. 9 shows such a catheter 20' with a central passage 21 for the delivery of diagnostic or therapeutic agents. 35

Hall at col. 3, lines 33-35.

target location. It would also be possible to automate the process, allowing the surgeon to input either a desired direction or location, and using a computer to control the magnetic field and the telescoping of the sleeve and the extension member. 30

Hall at col. 5, lines 30-34.

65 The movement of the sheath, the extension member, and even the stylette, can be automated and operated by motor instead of manually, if desired.

Hall at col. 6, lines 65-67.

25 The catheter can be provided with one or more electrodes for cardiac mapping, pacing, or ablation. Alternatively, the catheter can be used in some other procedure such as the delivery of therapeutic agents.

Hall at col. 2, lines 25-28.

The USPTO is characterizing Hall to “teach” the text of Dependent Claim 16, but does not support its characterization with objectively verifiable evidence, therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 16. What a reference “teaches” is a question of fact.^{82,83,84} Conclusory statements that a reference “teaches” something beyond

⁸² See *Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.”) (emphasis added).

⁸³ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”)

⁸⁴ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁸⁵ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);⁸⁶ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).⁸⁷ Even if the PTO personnel were to seek to support their

⁸⁵ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki’s tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board’s determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁸⁶ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

⁸⁷ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans

characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁸⁸ Thus, when a party to a matter asserts that a reference “teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted

application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁸⁸ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**”) (emphasis added)

teaching.^{89,90,91,92} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Hall do not recite the text of at least Clause [g] of Dependent Claim 16: “peristaltic wave.” Instead, Hall indicates “There is also at least one magnet, and preferably more than one magnet, on the distal end portion of the extension member to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field” (Hall Abstract). To Applicant, it appears that the USPTO has tried to close a significant gap between these actual recitations of the Hall reference and the structure of the “each distal end piece” and “peristaltic wave” (of Applicant’s Claim 16) without providing any evidence, by merely making this unsupported assertion.

⁸⁹ See *Rapoport v. Dement* 254 F. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

⁹⁰ See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

⁹¹ See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

⁹² See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

Applicant has shown by direct quotations that Dependent Claim 16 and the USPTO's citations are very different on their faces. *See supra* at p. 90 (quotation of Claim 16 with its parent claim); and at p. 93 *et seq.* (quotation of Hall). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 16, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 16 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Hall does not recite the text of at least Clause [g] of Applicant's Dependent Claim 16, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Hall could be modified/combined to teach at least Clause [g] of Dependent Claim 16, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 16 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Dependent Claim 16 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of the cited material, Applicant demonstrated above that the express recitations of the cited material are not as the USPTO alleges, and that the USPTO has provided no evidence—let alone the preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what the cited material “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, the USPTO has presented no evidence that the cited material teaches as asserted by the USPTO. In addition, Applicant respectfully points out that even if the USPTO's assertions regarding the teachings of the cited material were

supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of the cited material to the actual express language of Applicant's Dependent Claim 16. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 16 allowable and issue a Notice of Allowability of same.

Given that Applicant has shown, above, what the cited material actually recites, the question thus naturally arises as to how the USPTO saw the cited material as "teaching" something related to Clause [g] of Dependent Claim 16. Applicant respectfully points out that the Applicant's Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of the cited material as set forth, it follows that the USPTO is interpreting the cited material through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, the USPTO's assertions regarding the cited material are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 16 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO "teaches," Applicant infers that the USPTO is relying on "personal knowledge" and/or is taking "official notice" of one or more factors to reach the factual conclusion of what the cited technical material "teaches." In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting

forth objectively verifiable evidence in support of the USPTO's currently unsupported assertions regarding what the cited technical material "teaches" and/or should be interpreted to "teach." See, e.g., MPEP § 2144.03(C), *If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

As noted above, the USPTO has stated as follows:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to concert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009).

Although the USPTO states "Iddan teaches electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location," Applicant has pointed out above that the USPTO has not engaged in the broadest reasonable interpretation framework regarding Clause [g], and accordingly has not addressed at least the "two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend" recitations of Clause [d]. Accordingly, until the USPTO has supported its statement under the broadest reasonable interpretation framework Applicant here returns to the express language of the claim and thus respectfully points out that Applicant has reviewed the Iddan reference identified by the USPTO, and so far as Applicant can discern, the Iddan reference does not recite "two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend r" as recited in Applicant's Independent Claim 1.

Rather, the USPTO has not provided a citation as to where the alleged teaching “electroactive polymers suitable to concert [sic] electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location” might be found. Iddan discloses:

In operation, when positive voltage is applied to positive conductor 520A and first piezo material 512, the first piezo material 512 expands. When negative voltage is applied to negative conductor 520C and second piezo material 512, the second piezo material 512 contracts. As a result of current being applied to conductors 520A and 520C, the piezo element 510 bends, creating a radius of curvature.

Iddan at col. 14, lines 10-16.

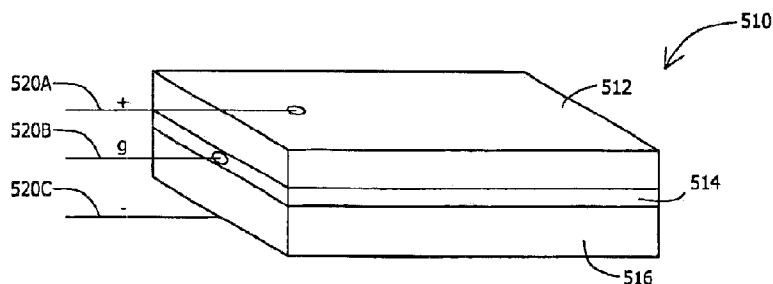


Fig. 6

Iddan Fig. 6.

Additionally, the USPTO is characterizing Iddan to “teach” at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence, therefore the USPTO has not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference “teaches” is a question of fact.^{93,94,95} Conclusory statements that a

⁹³ See *Rapoport v. Dement*, 254 F.3d 1053, 1060 (Fed. Cir. 2001) (“What a reference **teaches** is a question of fact... Therefore, we review the Board’s **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.”) (emphasis added).

⁹⁴ *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence). 1993) (reversing PTO and holding, when PTO presented no evidence to cure prima facie differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art “taught”).

⁹⁵ Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective evidence. *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009);⁹⁶ *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002);⁹⁷ *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (“Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. ... Broad conclusory statements standing alone are not “evidence.”).⁹⁸ Even if the PTO personnel were

⁹⁶ In *McNeil*, the Examiner had rejected claims reciting a tampon having “a generally cylindrical compressed, solid fibre core” and ribs “compressed less than the fiber core” in view of a Japanese patent application (“Sasaki”). McNeil appealed to the Board of Patent Appeals and Interferences, which “specifically found that ‘Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.’ ” *See id.*, 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being “compressed less than the fiber core,” the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that “Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward,” the Federal Circuit reversed the rejection for lack of “substantial evidentiary support,” stating as follows:

There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs “compressed less than the fiber core” or “a generally cylindrical compressed, solid fibre core.” ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other “at the proximal end by an amount greater than” than at “the distal end.”

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

⁹⁷ In *Lee*, the USPTO argued that, to the “common sense of a person of ordinary skill in the art,” it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game’s handbook. The Federal Circuit ruled that obviousness must be based on “objective evidence of record.” Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI’s obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

⁹⁸ In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference “teaches” something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such “teachings” unless they are supported by objective documentary evidence.⁹⁹ Thus, when a party to a matter asserts that a reference “teaches” something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to “close the gap” between what the reference

The Examiner cites Evans for teaching that “one *system* constructed and operated according to the invention may be used to control a number of valves.” Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that “one system” is equal to “one sensor.”

But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that “one system” is the same thing as “one sensor.” The words “sensor” and “probe” are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term “system” as a substitute for the simple temperature measuring device it calls “sensor.” And, the Board made no reference to any evidence in the record that would equate “one system” with “one sensor.”

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that “one system” is equal to “one sensor.” Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that “one system” means “one sensor.”

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

⁹⁹ *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (“The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**”) (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) (“For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**”) (emphasis added)

recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.^{100,101,102,103} For each instance below in which the USPTO has made an unsupported characterization, Applicant accordingly requests that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to “close the gap” between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Iddan do *not recite* the text of at least Clause [d] of Independent Claim 1: “two or more sensors, wherein the sensors are arranged to change a distance between at least two of the sensors as the one or more distal end pieces telescopically extend” and Clause [g] of Dependent Claim 16: “peristaltic wave.” Instead, Iddan recites “creating a radius of curvature.” Consequently, on its face, Iddan does not show the text of at least Clause [d] of Independent Claim 1 and Clause [g] of Dependent Claim 16. To Applicant, it appears that the USPTO has

¹⁰⁰ See *Rapoport v. Dement* 254 F.3d 1053, 1060 (Fed. Cir. 2001) . In *Rapoport*, the Federal Circuit affirmed the Board’s holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

¹⁰¹ See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO’s holding that a gene was “prima facie obvious over its corresponding protein” in the cited reference, absent any evidence of a one-to-one correspondence).

¹⁰² See *In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

¹⁰³ See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

tried to close a significant gap between this actual recitation of the Iddan reference and the “peristaltic wave” (in Clause [g] of Applicant’s Claim 16) without providing any evidence, by merely making this unsupported assertion.

Applicant has shown by direct quotations that Dependent Claim 16 and the Iddan reference are very different on their faces. *See supra* at p. 90 (quotation of Claim 16); and at p. 101 *et seq.* (quotation of Iddan). Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the USPTO-cited art is very different from Claim 16, and Applicant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 16 either under the MPEP or under controlling legal standards. *See supra* at pp. 23–36.

Accordingly, insofar as that Iddan does not recite the text of at least Clause [g] of Applicant’s Dependent Claim 16, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Iddan could be modified/combined to teach at least Clause [g] of Independent Claim 16, Applicant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 16 for at least these reasons. Thus, Applicant respectfully asks the USPTO to hold Dependent Claim 16 allowable and to issue a Notice of Allowability of same.

With respect to the USPTO assertions regarding the teachings of Iddan, Applicant demonstrated above that the express recitations of Iddan are not as the USPTO alleges, and that the USPTO has provided no evidence—let alone the preponderance of the evidence required—to support the USPTO assertions as to the factual conclusion as to what Iddan “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, the USPTO has presented no evidence that Iddan teach as asserted by the USPTO. In addition, Applicant

respectfully points out that even if the USPTO's assertions regarding the teachings of Iddan were supported, such would be of no moment in that the USPTO has yet to connect the alleged teaching of Iddan to the actual express language of Applicant's Independent Claim 1. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

Given that Applicant has shown, above, what Iddan actually recite, the question thus naturally arises as to how the USPTO saw Iddan as "teaching" something related to Clause [g] of Dependent Claim 16. Applicant respectfully points out that the Applicant's Application is the only objectively verifiable USPTO-cited document of record that shows or suggests what the USPTO purports the references to teach. From this and the express recitations of Iddan as set forth, it follows that the USPTO is interpreting Iddan through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, the USPTO's assertions regarding Iddan are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that the USPTO hold Dependent Claim 16 allowable and issue a Notice of Allowability of same.

As the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of the USPTO assertions regarding what the technical material cited by the USPTO "teaches," Applicant infers that the USPTO is relying on "personal knowledge" and/or is taking "official notice" of one or more factors to reach the factual conclusion of what the cited technical material "teaches." In view of the foregoing, if the USPTO desires to maintain the rejection, in the next communication, Applicant respectfully requests that the USPTO provide an affidavit or declaration setting

forth objectively verifiable evidence in support of the USPTO's currently unsupported assertions regarding what the cited technical material "teaches" and/or should be interpreted to "teach." See, e.g., MPEP § 2144.03(C), *If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence*, and 37 C.F.R. 1.104(d)(2).

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Hall and/or Iddan to meet the recitations of Dependent Claim 16, there can be no such teaching as a matter of law. Specifically, shown following is that (1) the USPTO's assertions regarding a teaching to modify/combine the technologies of Hall with the technologies of Iddan appear to be based on conclusory statement(s) without evidentiary support, (2) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall with the technologies of Iddan as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of one or more of the technologies; and (3) under the MPEP standards there can be no teaching to modify/combine the technologies of Hall with the technologies of Iddan as suggested by the USPTO in that such combination will render one or more of the technologies unfit for their intended purposes.

Furthermore, the USPTO-suggested modifications/combinations to meet the recitations of dependent claim 16 are a "mere conclusory statement" without evidentiary support. As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's "*analysis should be made explicit*" ... [*and that*] *rejections ... cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

As noted above, the USPTO has recently stated the following:

As to Applicant's arguments with respect to Claim 1:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 16:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009).

For reasons set forth above, Applicant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Hall and Iddan references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a “mere conclusory statement[.]” Applicant accordingly requests that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

With respect to this point, Applicant respectfully directs the USPTO to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In *re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.).

As noted above, the USPTO has stated as follows:

2. Claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (U.S. Pat. 6,385,472 B1).

Regarding claims 1-6, 8, 10, 21, 23-25, 27, 30, 32, 33-41, Hall discloses a system with a body portion (e.g., a body portion of a human, such as a circulatory system), an extending part with a proximal end piece and at least one distal end piece configured to telescopically extend from the proximal end piece; at least one receiving body; and a control circuit with a processor and stored software coupled to the receiving body (see Figs. 1 and 6; col. 3, lines 33-35; col. 5, lines 30-34) and suitable for controlling the system. The extending part comprises two or more distal pieces (see Fig. 1) and the distal end pieces are configured to slidably collapse within an interior of the proximal end piece; the extending part comprises a decreasing size and/or dimension for traveling the interior of a blood vessel (see Fig. 1); and the extending part comprises a hollow portion (see Fig. 1); the size of one or more distal end pieces is less than a size of a proximal end piece (see Fig. 1); the system further comprises a motor (col. 7, lines 65-67); the system further comprises a source of a chemical (col. 2, lines 25-28) and is capable of dispensing fluid through a dispenser at the end of the device; or a functional tool (46) and a tool positioner, which is capable of ablation (col. 2, lines 25-27).

Office Action, p. 2-3 (29 October 2009).

As to Applicant's arguments with respect to Claim 16:

Regarding claims 11-16, it is noted that Hall does not disclose a polymer operative for converting electrical energy into mechanical energy to move a fluid. Iddan teaches electroactive polymers suitable to convert electrical energy into mechanical energy so as to move a conduit containing a fluid receivable to a location. It would have been obvious for one of ordinary skill in the art at the time of the invention to implement the electroactive polymers of Iddan in the device of Hall so as to more accurately control a tractable conduit in a sensitive body orifice or vessel.

Office Action, p. 5 (29 October 2009).

Applicant respectfully asserts that one reason for Hall's lack of disclosure of "peristaltic wave" may be gleaned from principles of operation indicated in this recitation:

“There is also at least one magnet, and preferably more than one magnet, on the distal end portion of the extension member to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field” (Hall Abstract) (emphasis added).

Applicant respectfully points out that were one to incorporate the piezoelectric polymers as allegedly taught by Iddan into the structure of Hall, Hall would no longer be “oriented by the application of an externally applied magnetic field.” Thus, the USPTO-suggested modifications/combinations would change the principle of operation of Hall for at least this reason.

As discussed above, one reason why such modified Hall technologies would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to incorporate the structure of Iddan with the Hall technologies to provide a “peristaltic wave,” as recited in Dependent Claim 16. Hence, in addition to the USPTO-suggested modification/combination, there would need to be some type of reconstruction and/or redesign – appropriate to the capabilities of the structure and method of Hall – to provide for the structure of Iddan.

As has been shown above, the technologies of Hall modified/combined with the structure of Iddan as suggested by the USPTO would require “substantial reconstruction and redesign of the elements shown in [... Hall] as well as a change in the basic principle under which the [... Hall] construction was designed to operate” in order to render the USPTO-suggested combination capable of performing even a subset of the intended purposes of the technologies of Hall.¹⁰⁴

As has also been shown, even if the USPTO-suggested combination were to be somehow hypothetically modified such that the USPTO suggested modification/combination became somewhat workable, such a hypothetically

¹⁰⁴ This statement reflects Applicant’s current understanding. If Examiner can specify how such modifications/combinations can be implemented without substantially undermining any of Hall’s intended purposes, however, Applicant respectfully requests that such specification be included with the next Office Action.

modified version of the USPTO-suggested combination would itself require “substantial reconstruction and redesign of the [hypothetically modified] elements shown in [... Hall] as well as a change in the basic principle under which the [hypothetically modified] [...Hall] construction was designed to operate” in order to perform the intended function. Accordingly, insofar as that the USPTO-suggested modification itself would likely require at least one additional and as-yet-hypothetical modifications as explained above, under the MPEP standards set forth in block quote above, the USPTO’s suggested modification/combination “would change the principle of operation” of Hall’s technologies.

Insofar as that the USPTO-suggested modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render the USPTO-suggested modification/combination capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Hall will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such references to meet the recitations of Dependent Claim 16 as a matter of law. Accordingly, in light of the MPEP standards for patentability, Applicant respectfully requests that the USPTO hold Dependent Claim 16 patentable and issue a Notice of Allowance of Applicant’s Dependent Claim 16 for at least the foregoing reasons.

IV. CONCLUSION

Applicant may have during the course of prosecution cancelled and/or amended one or more claims. Applicant notes that any such cancellations and/or amendments will have transpired (i) prior to issuance and (ii) in the context of the rules that govern claim interpretation during prosecution before the United States Patent and Trademark Office (PTO). Applicant notes that the rules that govern claim interpretation during prosecution form a radically different context than the rules that govern claim interpretation subsequent to a patent issuing. Accordingly,

Applicant respectfully submits that any cancellations and/or amendments during the course of prosecution should be held to be tangential to and/or unrelated to patentability in the event that such cancellations and/or amendments are viewed in a post-issuance context under post-issuance claim interpretation rules.

Insofar as that the Applicant may have during the course of prosecution cancelled/amended claims sufficient to obtain a Notice of Allowability of all claims pending, Applicant may not have during the course of prosecution explicitly addressed all rejections and/or statements in Office Actions. The fact that rejections and/or statements may not be explicitly addressed during the course of prosecution should NOT be taken as an admission of any sort, and Applicant hereby reserves any and all rights to contest such rejections and/or statements at a later time. Specifically, no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended (e.g., with respect to any facts of which the USPTO took Official Notice, and/or for which the USPTO has supplied no objective showing, Applicant hereby contests those facts and requests express documentary proof of such facts at such time at which such facts may become relevant). For example, although not expressly set forth during the course of prosecution, Applicant continues to assert all points of (e.g. caused by, resulting from, responsive to, etc.) any previous Office Action, and no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended. Specifically, insofar as that Applicant does not consider the cancelled/unamended claims to be unpatentable, Applicant hereby gives notice that it may intend to file and/or has filed a continuing application in order prosecute such cancelled/unamended claims.

With respect to any cancelled claims, such cancelled claims were and continue to be a part of the original and/or present patent application(s). Applicant hereby reserves all rights to present any cancelled claim or claims for examination at a later time in this or another application. Applicant hereby gives public notice that any cancelled claims are still to be considered as present in all related patent application(s) (e.g. the original and/or present patent application) for all appropriate purposes (e.g., written description and/or enablement).

Applicant does NOT intend to dedicate the subject matter of any cancelled claims to the public.

Should this case go to appeal, Applicant reserves the right to submit argument, rebuttal evidence, or legal authority in the instance the Board of Patent Appeals and Interferences finds that the USPTO has met its burden in establishing a *prima facie* case of unpatentability of the various appealed claims. Applicant further reserves the right to submit argument, rebuttal evidence, or legal authority if new claim interpretations or definitional citations are raised on appeal. The fact that argument, rebuttal evidence, or legal authority may not have been explicitly discussed during the course of prosecution should NOT be taken as an admission or waiver of any sort, and Applicant hereby reserves any and all rights to discuss (e.g. make explicit, produce, or explain) such rebuttal evidence at a later time.

The USPTO is encouraged to contact the undersigned by telephone at 425-467-2284 to discuss the above and any other distinctions between the claims and the applied references, if desired. Also, if the USPTO notes any informalities in the claims, it is encouraged to contact the undersigned to expediently correct such informalities.

Respectfully submitted,

December 17, 2009
Date

/Mark Hennings, Reg. No. 48,982/
Mark R. Hennings
Registration No. 48,982